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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/613,443

07/03/2003

Eric A. Goldfarb

020489-000120US

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08/10/2006

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EXAMINER

POUS, NATALIE R

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,443	Applicant(s) GOLDFARB ET AL.	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 25-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-24 and 60-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/2/06, 2/13/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60128690, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for the claims of this application. The limitations of an apparatus having a pair of arms and a pair of superior arms to grasp the leaflets and keep them in a coapted configuration is not adequately disclosed in the provisional application to be used for priority.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-17, 21, 22 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Laufer (US 5810847).

Regarding Claim 13, Laufer teaches an apparatus for repairing a valve in a patient's body, the valve having a plurality of movable leaflets, the leaflets having a superior surface on a first side and an inferior surface on an opposing side, the apparatus comprising: a pair of arms (40, 42) coupled together and movable from an open position in which portions of the arms are spaced apart (fig. 4) to a closed position in which the portions of the arms are closer together (fig. 6), the arms being configured to engage the inferior surfaces of the leaflets and hold the leaflets in a coapted configuration (fig. 6) in which portions of the superior surfaces are facing each other; wherein the arms are implantable in the patient's body to maintain the leaflets in the coapted configuration (fig. 7).

Regarding Claim 14, Laufer teaches the apparatus of claim 13 further comprising a central member (50), the arms being movably coupled (53) to the central member.

Regarding Claim 15, Laufer teaches the apparatus of claim 14 wherein the arms are configured to clamp the leaflets between the arms and the central member in the closed position (fig. 6).

Regarding Claim 16, Laufer teaches the apparatus of claim 14 wherein the central member is configured to be positioned through the valve between the leaflets (fig. 6).

Regarding Claim 17, Laufer teaches the apparatus of claim 14 wherein the central member (50) is detachably coupled to a shaft (60) adapted for delivering the arms into the heart.

Regarding Claim 21, Laufer teaches the apparatus of claim 13 wherein the arms have engaging surfaces for engaging the surfaces of the leaflets (Column 5, proximate lines 43-44).

Regarding Claim 22, Laufer teaches the apparatus of claim 21 wherein the engaging surfaces have a texture or teeth for enhancing friction (Column 5, proximate lines 43-44).

Regarding Claim 66, Laufer teaches the apparatus of claim 21, wherein the arms engage the surfaces without penetration thereof Column 5, proximate lines 43-44).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18-20, 23, 24, and 60-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laufer in view of Kuehn (US 6165183).

Laufer teaches an apparatus for repairing a valve in a patient's body, the valve having a plurality of moveable leaflets, the leaflets having a superior surface on a first side and an inferior surface on an opposing side, the apparatus comprising the following:

- a pair of arms (40, 42) coupled together and moveable from an open position in which portions of the arms are spaced apart (fig. 4) to a closed position in which the portions of the arms are closer together (fig. 6), the arms being configured to

Art Unit: 3731

engage the inferior surfaces of the leaflets and hold the leaflets in a coapted configuration in which portions of the superior surfaces are facing each other (fig. 6); wherein the arms are implantable in the patients body to maintain the leaflets in the coapted configuration (fig. 6)

- the arms having engaging surfaces for engaging the surfaces of the leaflets (Column 5, proximate lines 43-44).
- the arms engage the surface of the leaflets without penetration thereof (Column 5, proximate lines 43-44).
- the engaging surfaces have a texture or teeth for enhancing friction (Column 5, proximate lines 43-44).
- the device is positionable through an endovascular sheath (Column 6, proximate lines 25-30).

Laufer fails to teach a pair of superior elements moveably coupled to a central member, the superior elements configured to engage the superior surfaces whereby the leaflets may be engaged between the arms and the superior elements and wherein the arms and the superior elements are moved independently of one another and are slidably positionable to the heart. Kuehn teaches an apparatus for repairing a heart valve in a patients body comprising arms (440) and a pair of superior elements (450, 452) coupled to a conduit (446) slidably coupled to a central member (456), independently moveable of the grasping arms, the superior elements resiliently biased into an extended configuration in which portions of the superior elements are spaced apart from the central member (fig. 20) in order to aid in guiding the leaflets to the

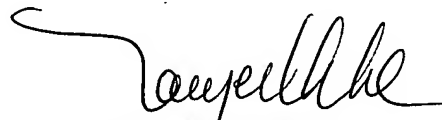
Art Unit: 3731

grasping arms (column 9, proximate lines 45-55). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Laufer with the superior elements as taught by Kuehn in order to aid in guiding the leaflets to the grasping arms.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER

7/24/06

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
7/11/06